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10/658,030

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Ivan W. Ong

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10/26/2006

EXAMINER

AUGHENBAUGH, WALTER

CLIFF D. WESTON

MICROBAN PRODUCTS COMPANY

1115 VANSTORY DRIVE

SUITE 125

HUNTERSVILLE, NC 28078

ART UNIT

PAPER NUMBER

1772

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/658,030

Applicant(s)

ONG, IVAN W.

Examiner

Walter B. Aughenbaugh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006 and 26 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-12 and 20-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12 and 20-34 is/are rejected.
- 7) ☒ Claim(s) 20 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Acknowledgement of Applicant's Amendments***

1. The amendments made in claims 10-12 in the Amendment filed July 26, 2006 (Amdt. B: Response to Notice of Non-Compliant Amendment) have been received and considered by Examiner.
2. New claims 20-34 presented in Amdt. B have been received and considered by Examiner.

### ***WITHDRAWN OBJECTION***

3. The objection to claim 6 made of record in paragraph 2 of the previous Office Action mailed November 29, 2005 has been withdrawn due to Applicant's cancellation of claim 6 in Amdt. B.

### ***WITHDRAWN REJECTIONS***

4. The 35 U.S.C. 112 rejection of claims 7 and 8 made of record in paragraph 4 of the previous Office Action mailed November 29, 2005 has been withdrawn due to Applicant's cancellation of claims 7 and 8 in Amdt. B.
5. The 35 U.S.C. 102 rejection of claims 1-9 made of record in paragraph 6 of the previous Office Action mailed November 29, 2005 has been withdrawn due to Applicant's cancellation of claims 1-9 in Amdt. B.

### ***REPEATED REJECTION***

#### ***Claim Rejections - 35 USC § 102***

6. The 35 U.S.C. 102 rejection of claims 10-12 made of record in paragraph 6 of the previous Office Action mailed November 29, 2005 has been repeated for the reasons previously made of record and for the following reasons that address the amendments in claim 10 in Amdt.

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B: the recitation “sized for fluid carriage in a garden use” is an intended use phrase that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987). The remainder of the recitations added to claim 10 in Amdt. B are addressed in paragraph 6 of the previous Office Action mailed November 29, 2005.

### ***NEW OBJECTIONS***

#### ***Specification***

7. The amendment filed November 29, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the material of new claims 24-28, 33 and 34 that is identified as new matter in the 35 U.S.C. 112, first paragraph, rejection of claims 24-28, 33 and 34 made of record in this Office Action.

Applicant is required to cancel the new matter in the reply to this Office Action.

#### ***Claim Objections***

8. Claims 20 and 24 objected to because of the following informalities:

In regard to claim 20, “said first tube” should be amended to “said tube” to make the language of the claim consistent.

In regard to claim 24, “antimicrobial hose” should be amended to make the language of the claims consistent since claim 20 does not characterize the hose as an “antimicrobial hose”.

Appropriate correction is required.

***NEW REJECTIONS***

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 24-28, 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In regard to claim 24, the recitation “has an outer diameter of at least about 0.5 inch” is not supported in the specification as originally filed.

In regard to claim 25, the recitation “the first antimicrobial agent being an inorganic antimicrobial agent” is not supported in the specification as originally filed. The disclosure of “metallic antimicrobial agents” in paragraphs 14, 20 and 38 is not equivalent to a disclosure of inorganic antimicrobial agents.

None of the limitations of claims 26 and 27 are supported in the specification as originally filed.

In regard to claim 28, silver zeolite is the only agent recited in claim 28 that is supported in the specification as originally filed (in paragraphs 20 and 38). All other agents recited in claim 28 are not supported in the specification as originally filed.

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In regard to claim 33, an embodiment where an inorganic antimicrobial agent and any antimicrobial agent described in the specification are both in the polymeric composition is not supported in the specification as originally filed. An embodiment where a metallic antimicrobial agent and any antimicrobial agent described in the specification are both in the polymeric composition is also not supported in the specification as originally filed. The only embodiment where two antimicrobial agents are both in the polymeric composition that is supported in the specification as originally filed is the embodiment where both chlorinated phenols are in the polymeric composition (paragraphs 22 and 39).

In regard to claim 34, the recitation of "an inorganic compound" as the second antimicrobial agent is not supported in the specification as originally filed. The disclosure of "metallic antimicrobial agents" in paragraphs 14, 20 and 38 is not equivalent to a disclosure of inorganic antimicrobial agents. In further regard to claim 34, silver zeolite is the only inorganic compound recited in claim 34 that is supported in the specification as originally filed (in paragraphs 20 and 38). All other inorganic compounds recited in claim 34 are not supported in the specification as originally filed.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 34 recites the limitation " the second antimicrobial agent " in the first-second lines of the claim. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claims 20-23 and 25-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Modak et al. (USPN 5,772,640).

In regard to claims 20 and 21, Modak et al. teach a hose comprising a tube constructed of a thermoplastic polymer composition wherein the composition comprises polyvinyl chloride and 2,4,4'-trichloro-2'-hydroxy diphenyl ether (triclosan, col. 4, lines 15-21 and col. 3, lines 8-9, note that Applicant states in the specification that 2,4,4'-trichloro-2'-hydroxy diphenol ether is also known as triclosan on page 6, lines 1-2; triclosan corresponds to the claimed one organic antimicrobial agent) (col. 4, lines 15-29 and col. 3, lines 54-57). The term "garden" in the recitation "garden hose" renders the recitation "garden hose" an intended use phrase that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987). The recitation "sized for fluid carriage in a garden use" is an intended use phrase that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987).

In regard to claims 22 and 23, Modak et al. teach that the triclosan is present in an amount of between 0.5 and 5% of the weight of the treatment solution (col. 15, line 55-col. 16,

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line 2), range that overlaps with the claimed ranges of “from about 200 ppm to about 10,000 ppm” (equivalently, between about 0.02% and about 1%) and “from about 500 ppm to about 5,000 ppm” (equivalently, between about 0.05% and about 0.5%).

In regard to claim 25, Modak et al. teach a hose comprising a first tube of a thermoplastic polymer composition wherein the composition comprises polyvinyl chloride and a first antimicrobial agent that is an inorganic antimicrobial agent (col. 4, lines 15-29 and 40-43 and col. 3, lines 54-57). The term “garden” in the recitation “garden hose” renders the recitation “garden hose” an intended use phrase that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987). The recitation “sized for fluid carriage in a garden use” is an intended use phrase that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987).

In regard to claims 26 and 27, Modak et al. teach that the first antimicrobial agent is a silver compound (col. 4, lines 40-43).

In regard to claim 28, Modak et al. teach that the first antimicrobial agent is elemental silver (col. 4, lines 40-43).

In regard to claims 29 and 30, Modak et al. teach that the silver compound is present in an amount of between 0.5 and 1% of the weight of the treatment solution (col. 4, lines 40-43), range that overlaps with the claimed ranges of “from about 200 ppm to about 10,000 ppm”



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(equivalently, between about 0.02% and about 1%) and “from about 200 ppm to about 5,000 ppm” (equivalently, between about 0.02% and about 0.5%).

In regard to claim 31, Modak et al. teach that the hose comprises a second tube (coating) disposed substantially concentrically on an outer aspect of the first tube and surrounding the first tube (col. 4, lines 15-29 and col. 3, lines 54-57).

In regard to claim 32, Modak et al. teach that the second tube (coating) is substantially free of antimicrobial agents (col. 4, lines 15-29 and col. 3, lines 54-57).

In regard to claim 33, Modak et al. teach a second antimicrobial agent incorporated in the thermoplastic polymer composition of the first tube (triclosan, col. 4, lines 15-21 and col. 3, lines 8-9, note that Applicant states in the specification that 2,4,4'-trichloro-2'-hydroxy diphenol ether is also known as triclosan on page 6, lines 1-2).

Claim 34 cannot be treated on its merits due to the indefiniteness of claim 34 (see 35 U.S.C. 112, first paragraph, rejection of claim 34 made of record in this Office Action).

### ***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al. (USPN 5,772,640) in view of Sisley et al. (USPN 4,405,313).

Modak et al. teach the hose as discussed above. Modak et al. teach that the hose may be a catheter (col. 3, lines 10-17).

Modak et al. fail to teach that the hose has an outer diameter of at least about 0.5 inch.

Sisley et al. teach that an inside diameter of about 0.5 inch is a suitable inside diameter for catheters for the aorta (col. 4, line 67-col. 5, line 2). Since a catheter having an inside diameter of approximately 0.5 inch necessarily has an outer diameter of greater than approximately 0.5 inch, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the catheter of Modak et al. such that it has an outer diameter of greater than about 0.5 inch, depending on the desired end use of the catheter, for example, when the desired end use of the catheter is a catheter for the aorta, since an inside diameter of about 0.5 inch is a suitable inside diameter for catheters for the aorta as taught by Sisley et al.

### ***Response to Arguments***

17. Applicant's arguments presented on pages 8-9 of the Amendment filed May 1, 2006 (Amdt. A) regarding the 35 U.S.C. 102 rejection of claims 10-12 have been fully considered but are not persuasive.

Applicant's discussion regarding the "*Synergistic Combination*" alleged to be taught by Modak et al. is not relevant to the rejection of record since it is a rejection under 35 U.S.C. 102.

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Applicant cites MPEP 2143.01, but MPEP 2143 pertains to the requirements for a *prima facie* case of obviousness, and therefore, rejections under 35 U.S.C. 103, not under 35 U.S.C. 102.

Applicant admits that “[t]he specific claimed diameter is not explicitly recited in the specification”, but “Applicant requests that the Examiner take official notice of the fact that garden hoses routinely are found in [certain diameters]”. Applicant’s recitation of a minimum outer diameter in claim 24 constitutes new matter because the recitation “has an outer diameter of at least about 0.5 inch” is not supported in the specification as originally filed. The size of the hose is not contemplated in the specification as originally filed. Applicant has not cited authority which permits Applicant to request that the Examiner to take official notice of the requested subject matter nor has Applicant cited authority which permits Examiner to take such official notice.

The term “garden” in the recitation “garden hose” renders the recitation “garden hose” an intended use phrase that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987). Applicant has not explained how Applicant’s arguments regarding the “significant factors” mentioned by Applicant at the bottom of page 8 of Amdt. A rebut the 35 U.S.C. 102 rejection of record.

Applicant’s arguments at the top of page 9 of Amdt. A are directed to a 35 U.S.C. 103 rejection (“[o]ne of ordinary skill”, “obvious”...), so these arguments do not address the 35 U.S.C. 102 rejection of record.

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Applicant's discussion regarding the alleged "*Time-Released Antimicrobial Agent*" of Modak et al. is not relevant to the rejection of record since it is a rejection under 35 U.S.C. 102. Modak et al. teaches the structure and composition claimed in claims 10-12.

Applicant's discussion of Milner '442 is not relevant to any of the rejections of record since Milner '442 is not relied upon in any of the rejections of record.

18. The Declaration under 37 CFR 1.132 of Duane T. Centola filed May 1, 2006 is insufficient to overcome the rejection of claims 10-12 based upon 35 U.S.C. 102 as set forth in the last Office action because the claims are rejected under 35 U.S.C. 102. Modak et al. teaches the structure and composition claimed in claims 10-12. A 35 U.S.C. 102 rejection cannot be overcome by a Declaration under 37 CFR 1.132. MPEP 706.02(b), 716. Applicant has not identified the Declaration as a Declaration under 37 CFR 1.132, but the nature of the Declaration appears to be that of a Declaration under 37 CFR 1.132.

19. The Declaration of Clifford D. Weston filed May 1, 2006 does not establish that the subject matter of claim 24 is supported in the specification as originally filed. Applicant admits that "[t]he specific claimed diameter is not explicitly recited in the specification", but "Applicant requests that the Examiner take official notice of the fact that garden hoses routinely are found in [certain diameters]". Applicant's recitation of a minimum outer diameter in claim 24 constitutes new matter because the recitation "has an outer diameter of at least about 0.5 inch" is not supported in the specification as originally filed. The size of the hose is not contemplated in the specification as originally filed. Applicant has not cited authority which permits Applicant to request that the Examiner take official notice of the requested subject matter nor has Applicant cited authority which permits Examiner to take such official notice.

***Conclusion***

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is to 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh

10/23/06

WBA



JENNIFER MCNEIL  
SUPERVISORY PATENT EXAMINER

10/24/06